National Children's Study
National Association of County and City Health Officials Conference Call
December 16, 2004

MS. SHREEVE: Good afternoon to all of you. Good morning to those of you who are joining us from the West Coast. My name is Chris Shreeve, and I'm here today on behalf of the National Children's Study to welcome you to today's call.

This is the second of two calls that the National Children's Study Program Office is conducting this week with participating counties. There was a call yesterday with officials from your individual counties, and I think in that call we had nearly 30 Study sites participating. I think we have an even bigger group of people listening in today.

I'd just like to go over a few details before I introduce today's speakers. First, as you heard from the operator when you called in, if you're having any difficulty with your line, please press *0 and someone will help you. At the end of today's speakers' remarks, we'll open up the forum for your questions. To ask a question, remember, press 1 and an operator will then line you up and tell you what to do. We'd like to ask you, if you could, when the line is given to you and you can speak, to introduce yourself and please identify the county that you're coming from for the benefit of those of us who are listening.

Second, I want to let you know that today's session will be recorded, and a transcript may be posted to the National Children's Study Web site. Just wanted to make sure you all know that.

And finally, I want to remind you that the National Children's Study sent you a FedEx packet of background materials last month. These packets were signed by someone in your office. You may not have received them. If you didn't, you can find the same information on the Web at www.nationalchildrensstudy.gov.

Now I'd like to introduce today's speakers from the National Children's Study Program Office. First you'll hear from Dr. Peter Scheidt, who's the program director for the National Children's Study. He'll give you a brief introduction to the Study and talk to you a little bit about its goals and benefits. He'll be followed by Jim Quackenboss, an environmental scientist, who will speak next on how the Study locations were chosen. So you can ask him those kinds of questions. And finally, Sarah Keim, Study coordinator, will tell you about the timeline for the Study and how your county can get involved in the Study.

Each of these speakers will speak for about 5 minutes and then we'll open up the call to your questions. Thank you very much. Dr. Scheidt?

DR. SCHEIDT: Hello. Good afternoon, and thank you very much for joining us. Our time is very limited and so I'm only going to give the very briefest summary of the background and the development of the National Children's Study that I hope will answer at least a few of the questions that you may have.

The National Children's Study will help pinpoint the causes and environmental contributions of many of today's childhood and adult diseases and disorders. We aim to provide researchers and health care providers and others who've worked with children an extensive resource from this study of data, which will develop prevention strategies and health and safety guidelines and educational approaches for possible new treatments and cures for health conditions in the development and care of our children.

One of the most frequent questions that I'm asked in talking about the National Children's Study is how did this begin, how did it start. It started, really, with very thoughtful and very high-level considerations. The first concrete proposal for this study began with a task force convened by the president in the late 1990s that has also been reappointed by the current president twice. And so it very much spans the past several administrations.

This task force was composed of nine of the cabinet officers in the President's cabinet and was charged with developing national strategies to reduce and control the risks of environmental exposures to children. This concern was based on known and important environmental exposures for which there were considerable concerns of a wide range and character, and it was based on concerns about a number of conditions and diseases in children which are problematic and important and for which there are concerns about possible environmental contributions and causes.

When the task force confronted the need for these strategies to reduce the risks to our children, they realized that they simply did not have the information and the science in order to provide this guidance, and they proposed a kind of research program that could provide the information, the data, that can then guide both health care and policy. A consultation with many of the large longitudinal studies around the world and with representatives from all similar studies reaffirmed the need and timeliness of undertaking this study, and then Congress reaffirmed this recommendation with inclusion in the Children's Health Act of 2000, authorizing that this study be planned and implemented.

The National Children's Study will be the first study ever, of this size, to capture exposures both prior to and early in pregnancy, and then track its 100,000 participants for 21 years, from early in pregnancy to adulthood.

The planning of this has been carried out with a consortium of all those federal agencies with a concern about children's health, including four lead agencies: along with NICHD, the Centers for Disease Control, the U.S. Environmental Protection Agency, and the National Institute of Environmental Health Sciences, and forty other Cabinet departments, NIH institutes, CDC centers, and EPA offices.

A number of carefully developed hypotheses have been developed, and the Study will also, in addition to hypotheses, serve as a national resource for future hypotheses and studies for decades to come.

The data collection will involve measures of environmental exposures that will be tracked and analyzed in relationship to a variety of health outcomes.

The environmental exposures will include biological exposures such as nutrition and infection, chemical exposures of a wide variety of those that are concerned, psychological exposures, measures of genetic data and information, that will all be collected and measured and tracked for relationships with outcomes of pregnancy, such as preterm birth, stillbirth, and birth defects, and for development of children, such as autism, learning disabilities, depression and schizophrenia, children's growth and nutrition, such as obesity and sexual development, and also including asthma and injuries.

These data from the Study locations across the country will be compiled and reported on a national basis. Counties will not be compared to each other. Data for one county or site will not be released independently, but if recognizable risks are identified that affect a county, we do anticipate and expect to inform county officials for the benefit of that county, and the same goes for individuals. As information becomes known of known risks, individuals will be informed so that steps could be taken to reduce those risks.

By being a part of the National Children's Study, your county will be contributing to the future of America's health. The families in your county will be participating in this landmark study, which will enable you to learn more about the health of your community and of all America's children as well as your own county. The Study will be bringing state-of-the-art resources to the community in order to learn about and understand [audio blip] environments.

Well, who participates and how are they selected? A great deal of thought, work, and consideration has gone into developing the sample of which you are a part. First, let me say we felt and concluded that it was very important to understand facts and attributes of the counties across the kinds of exposures that we're proposing.

The kinds of chemical exposures, the physical environment, and the social, cultural environments of your communities, and of the community in which children live, and in order to do that we need to collect information from more than one participant in each community—from a number of participants in each community. And so the Study is organized by clusters of communities rather than being widely dispersed across all counties of the country. And think of it, if you will, for those of you who may be familiar with the Framingham study, as a multiple 96 Framinghams across the country.

Secondly, it was important that the exposure-outcome relationships—the primary concerns of this study—be representative of those experienced by the U.S. population. Therefore, it was important that the participants and the sample be a probability sample, and that it is in fact representative of the U.S. population.

Furthermore, the exposures of concern in the Study are so wide and varied, and their distribution unknown, that we concluded the best way to not miss important exposures was to have a

representative sample that represents those exposures experienced by the total of the U.S. population.

To carry out the Study, it was important that we have broad scientific input, and that we be able to carry out detailed and sometimes demanding measures and incorporate the expertise and facilities of centers, and therefore we chose a center-based approach to implementing the Study with a national probability sample.

To tell more about how that sample was developed, and in more detail, Mr. Quackenboss will talk to you now. Jim.

MR. QUACKENBOSS: Thank you, Pete.

Good morning, and good afternoon, depending upon what part of the country you're in.

As Pete mentioned, there was considerable thought, debate, and input from the scientific community with experts in epidemiology, biostatistics, and different types of study designs, which went into the decision to select the Study locations as a national probability sample.

To do this, we looked at the listing of all counties, or their equivalents in the United States, and from that identified characteristics of those counties based on the Census information and on the natality or birth records maintained by the National Center for Health Statistics.

A sampling statistician at the National Center for Health Statistics stratified the counties by various characteristics, including the race, ethnicity, and percentage of babies born at low birth weight, and also looked in terms of breakdown by different parts of the country, and areas that had rural or, excuse me, nonmetropolitan areas and metropolitan areas.

Based on these lists and those strata, he selected 96 locations that were chosen to represent the characteristics of the United States in this study.

Your location was included through the use of this probability sampling method, and what we were trying to do, as Pete mentioned, was to ensure that the 100,000 children that are recruited in this study are representative the face of all of America's children and that we're able to evaluate and extrapolate the exposure-response relationships—evaluate it in this study—to a much wider group.

The locations roughly correspond to counties, or in some cases we have clusters of rural counties in order to obtain enough live births over the period of enrollment, and that period would be approximately 4 years for the main, or for the Study sites, with the vanguard centers having an additional year.

As I mentioned, in addition to population size, we looked at the geographic region of the country, using the Census regions and divisions, and then demographic variables. Although not every county, nor even every state is represented among these locations, it's important to

emphasize that everyone will benefit from the results of the National Children's Study. The findings from this can be applied to look at the health and environmental issues anywhere in the country.

With that, I'm going to turn it over to Sarah Keim to discuss the Study timeline.

MS. KEIM: Thanks, Jim.

At the same time that we sent out a packet of information to you around November 16th, last month, we posted requests for proposals to seek institutions who are interested in serving as Study centers for the vanguard locations.

And these vanguard locations, just to reiterate, are a small selection of locations from among the 96. These are the locations that the request for proposals refers to, and we will be selecting a subset of these eight potential vanguard locations to serve as the initial Study sites for the National Children's Study.

The procurement process for these is going on right now, and we're hoping to award the contracts to institutions sometime around August or September of 2005. I want to be very clear that this procurement is open to all institutions or organizations that can perform the work described in the request for proposals and can demonstrate capability in working with local communities.

Of the eight potential vanguard locations, the actual number of centers awarded will depend on funds available. We're thinking now probably three to five of the eight will be awarded next August or September. If you have questions about participating in these procurements, I refer you to a contact here at the National Institute of Child Health and Human Development, and I will give you her name and phone number now. Her name is Virginia DeSeau. Her phone number is 301-435-6947. That's Virginia DeSeau, 301-435-6947. And like I said, she can answer any questions you have about these requests for proposals and the procurement process and what's involved in seeking a contract.

As I mentioned, the vanguard locations will be the first to be implemented. And then, depending on funding over the next year or so after that, the remaining locations will be engaged on a rolling basis. All recruitment for the Study will take place between 2007 and 2011, over that 5-year window.

Upon award of the Study contracts, vanguard centers will start preparing for recruitment. That will happen through 2006. Those centers will be expected to work with their community leaders to communicate about the Study to potential participants, with a goal of starting recruitment in very early 2007 in these vanguard locations.

We've had some questions from counties about what their particular role can be in this process, now and in the future. I want to make sure you're aware that it's very much up to you. Like I said, the procurements are open to anyone who would like to submit a proposal to be a vanguard

location, and that includes county governments as well. But that is definitely not a requirement. We want to be clear that we understand that you have a lot of burdens on you and are very busy. Some counties have expressed an interest in taking on actually serving as a center, while others have been interested in some other types of involvement. So I want to mention what some of those other possibilities might be, if you are interested in them.

First off, I'd like to mention a bit about where you can learn more about the Study. Again, our Web site is www.nationalchildrensstudy.gov. And the materials that we sent out to you in November are available there in electronic form right from the home page. So if you didn't receive a packet or no longer have it, you can get the materials there from our Web site.

As we move closer to recruitment, we'll be developing more materials geared toward potential participants or things that might be of interest for you to distribute to people in your community. For right now, if you'd like to discuss more about acquiring some materials to spread the word about the Study or just have general questions about the Study, you can give me a call in the National Children's Study Program Office. Again, my name is Sarah Keim. My phone number is 301-594-9147. That's 301-594-9147. You may be interested in serving as a local resource of information about the Study, and I can help you do that if you're interested.

We firmly believe that the Study will only be successful if communities are supportive and engaged in the effort. We think it's going to take the efforts of all levels of government—federal, state, and local—as well as universities and schools, nonprofit organizations and foundations, industry, the medical community, and research communities to make the Study a success.

Another way you can get involved now if you are interested—and we've seen a couple of communities take this up on their own—some counties have put out press releases noting their selection of a Study location and have expressed an interest in speaking with local media. If that is of interest to you, we can help you by providing any sort of content or information to carry that out.

If your county itself is not interested in submitting a proposal to be a vanguard location—which is probably quite common—and you know there are other institutions in your area that may be interested or you think should know about this, feel free to pass along information to them. Let me just mention very quickly where the requests for proposal information, as well as our Study Plan, is posted. That is at the following Web site: www.fedbizopps.gov. You can also get there from the National Children's Study Web site. That has all the materials and instructions on how to submit proposals to be a vanguard site.

We also have requests for proposals to serve as a central coordinating center for the National Children's Study. That is also posted there at this time.

I think it's time now to open up the line for questions.

OPERATOR: Our first question comes from Richard Vogt in Douglas County. Your question, please.

QUESTIONER: Yes, hi. I'm Dr. Richard Vogt. I'm the executive director of the Tri-County Health Department that serves Adams, Arapahoe, and Douglas County. I just wanted to reconfirm what I thought I heard you folks say: There will not be any information available at the county level. And if that's the case, it's going to be more challenging to get buy-in into this particular process, because it would be very helpful to have county-specific information.

DR. SCHEIDT: We stated that the counties would not be provided county-specific information, feedback, except for your own county. So where we learn information useful to the county, it would be provided to the county. But we would not be providing counties information about other counties so that they would compare among themselves. We would provide information about the entire study so that a county might compare itself to all of the participating counties taken together as a whole. Does that clarify it?

QUESTIONER: That's helpful. I'm very pleased to hear that we may be able to have information about our own county.

MODERATOR: Sir, did you have anything further?

QUESTIONER: No. I think that'll be helpful.

MODERATOR: Our next question comes from Glennah Trochet in Sacramento County.

QUESTIONER: Yes, thank you. I would just like to know, I had the same question as the previous questioner, but my second question is as you recruit these children, here in Sacramento, many children move in and out of county. Or will you just be following them wherever they may move throughout the course of the Study?

DR. SCHEIDT: Yes. This is Peter again, and we do anticipate following children after they move. When they move within reach of one of the other centers, the responsibility for following them can be transferred from one center to another, and we anticipate and have planned for doing that.

When they move to areas of the country that are not covered or accessible from another center, the clinical coordinating center has the responsibility of following up with them as well, and the qualifications of the clinical coordinating center are very clear, that they must be prepared and capable of stepping in to do this kind of thing. So we know we'll lose some participants by moving, but we hope by these procedures to minimize that loss.

QUESTIONER: Thank you. May I ask another question?

DR. SCHEIDT: Yes.

QUESTIONER: Okay. My other question is for those counties that are not vanguard counties, what is your recommendation as far as the public announcement of this program, and what kinds

of communications do you believe we should be doing, because this may not start for us for another year?

MS. KEIM: That's a great question. We've noticed in some communities that have, in particular, for instance, had some press coverage locally, noting the fact that the county had been chosen as a Study location, and I've felt that's been a very positive thing in those communities; we think that it's reasonable for citizens to know about this early on. Obviously it's important also to understand that recruitment and enrollment won't happen for a little while yet.

I think another area that may be important, depending on how things are in your community, is whether practitioners maybe could benefit from knowing about this very early on, and that may be something to think about. We can help you with information to be able to do that, if you think practitioners in your area would benefit from knowing.

So it's probably not a bad idea for people to know about it early, but expectations need to, you know, be appropriate to when recruitment would actually begin. I hope that's helpful a little bit.

I think you probably know your community better than we do, for sure, so if we can be a resource in that, we're very willing to do that.

DR. SCHEIDT: Let me add that it was necessary to announce where the Study would be conducted, and the sites, in order for potential centers to be able to understand what would be required of them, and whether or not they could anticipate to be a center for the vanguard studies versus a center for those sites that come later. And because of the importance of making those judgments and preparing appropriate proposals, it was necessary to announce this.

QUESTIONER: I'm a little confused now. I thought you had already determined what counties would be the vanguard.

DR. SCHEIDT: Yes; we have.

QUESTIONER: It would be centers in those counties that—

DR. SCHEIDT: Yes. We have determined the sites that can be possible vanguards. The exact center that will carry out the work will be determined by the announcements on a competitive basis for centers to carry out the work in those respective eight sites.

MS. KEIM: But they don't need to be located in that exact county. So they may be thinking about—we thought it was important that they understood where all the locations were, so that they could think about if there's several in their general region, which of them they'd be most capable of carrying out the Study.

QUESTIONER: Thank you.

MODERATOR: The next question comes from the line of Ann Lindsay in Humboldt County.

QUESTIONER: Yeah. My question's been answered. Thank you.

MODERATOR: Our next question is from Chris Kippes in Cuyahoga County. Your question, please.

QUESTIONER: Yes. Earlier, you referenced the meeting that occurred yesterday and I was wondering if you could tell me the differences in the meeting that occurred yesterday versus today's meeting?

MS. KEIM: They were very similar. Obviously we're not receiving the exact same questions because we have different people on the line. We're creating a transcript of both of those that we'll post on our Web site, so you can have an opportunity to read about the exact words that were spoken on the call yesterday. But very similar—we presented the same information.

DR. SCHEIDT: However, the invitees yesterday were the county officials, the executive officers, and the, you know, the—

MS. KEIM: County board.

DR. SCHEIDT: —county executives, whereas this meeting was aimed for the county health officers.

QUESTIONER: Okay.

MODERATOR: The next question comes from Mark Horton in Orange County.

QUESTIONER: Yes; thank you. In some of the materials that I reviewed, I think I read that each site was going to be expected to recruit 250 individuals per year over a 5-year period. My question was whether that number was independent of the size of the county.

MR. QUACKENBOSS: Pete, do you want me to take that one?

DR. SCHEIDT: Yes, Jim, go ahead. But which Orange County?

QUESTIONER: Orange County, California.

MS. KEIM: Okay; thanks.

MR. QUACKENBOSS: I'm going to be visiting you next week.

QUESTIONER: Great.

MR. QUACKENBOSS: Yes, it is independent. It's a target for each of the—what were identified as primarily sampling units. Those, however, took into account the size of the counties in their probability of selection into the sample.

Large counties like yours will have a second stage of selection to identify communities, or in sampling terms, the area segments that would be selected at the second stage of selection, and then within that we would expect—and so in your area, that may be, again, looking at the size of the area, the demographic characteristics, possibly some environmental factors. First, we want to make sure we identify boundaries for the communities that make sense and we're going to need help from the local area, the local center in doing that.

Then the coordinating center will draw a sample within the larger counties and that would allow a sufficient number of women of childbearing age to then be able to obtain approximately 250 births per year over the 5-year period. The target for each of the Study areas was on the order of a 1,000 births over a 4-year period.

For smaller counties, that will be, you know, a large percentage of the births, and indeed, for some of the very small nonmetropolitan counties, we've had to combine multiple counties to have numbers that would provide sufficient numbers of births.

QUESTIONER: Thank you. That's helpful.

DR. SCHEIDT: You're welcome.

MODERATOR: We have a question from Portia Choi in Kern County.

DR. SCHEIDT: I'm sorry. Which county?

QUESTIONER: Kern County. It's in California, just north of Los Angeles.

DR. SCHEIDT: Kern; yes.

QUESTIONER: And we're part of the fabulous Central Valley. And my questions have been already answered. Thank you.

DR. SCHEIDT: I'm glad you're proud of your county.

MODERATOR: We have a question from Sherri McDonald in Thurston County.

QUESTIONER: In Thurston County in Washington state. We're from a public health department and I want to get just a little bit more information, if it's possible, about the role that we might play. I understand that it's as much or as little as we might define, but what I heard was, act as a local information resource, work with media perhaps, but my question is: is there a better definition of what roles we might play in, say, for instance, recruitment, or anything else? What are the possible roles?

MS. KEIM: I think that will become much more clear when we have a Study center lined up for that, for your Study location. They'll bring resources to the table in terms of outreach and interaction with the community, and you obviously have a lot of resources in that regard too.

And I think when we know what institution or organization is lined up to do that, I think it'll be sort of a collaborative effort to think about what will be needed to have a successful recruitment in your area.

DR. SCHEIDT: In addition, let me say that the Study centers are expected to involve and engage many components of the communities where the Study will be carried out, and that may be partnership kinds of arrangements or including them in the development of proposals, or in various ways to help carry out the proposals, using registers of citizens in the county, households in the county as a source of identifying participants—with participation in reimbursement, the capacities of these various entities, including health departments.

So a number of those possible arrangements can be anticipated. We don't have a prescription of what they must be, however. We're looking for the local centers and the local sites to propose arrangements and procedures that are most effective for the local counties.

QUESTIONER: Can I ask one follow-up question about the Study centers? I understand that you put out a request for proposal—

DR. SCHEIDT: That's correct.

QUESTIONER: —for the vanguard locations and so my question is: can you just give a brief summary of those Study centers that will be selected, maybe do you anticipate it would be the same for the vanguard centers as for the following sites, or do you anticipate that you would stick with the same ones, or does it depend on something? And basically what are you looking for as far as the Study centers?

DR. SCHEIDT: The selection process will be a competitive one. We're required to do that, and we think that's the most effective way to identify the most capable entity to carry out this work. We anticipate a number of them are likely to be academic centers—you're from Washington, such as the University of Washington Medical Center—but others as well: strong county health departments, regional hospitals—a variety of entities.

And that will be on a competitive basis, and the more potential centers there are within range of a designated site, the more proposals there will likely be and the greater the competition.

That same process will be used for both the vanguard centers and for the subsequent centers, and it's not anticipated that it's a given that the vanguard centers will necessarily expand to nearby areas. Those will be, if there are adjacent or nearby Study sites selected as the sample, that will still be a competitive basis. Does that help answer the question?

QUESTIONER: Yes, it does and I would assume that the request for proposal is posted on the Web site?

DR. SCHEIDT: Yes; it is.

QUESTIONER: Thank you.

MODERATOR: The next question is from Dalton Savroy in Orleans Parish.

QUESTIONER: Yes; thank you. I also have a concern about the role of public health. We do operate some family planning clinics. I notice that one of your recruitment goals would be to recruit 100,000 children in utero, and track them to development for 21 years as such, and I don't know what type of public health clinic you might be interested in using. And then I also gather that we could do a cooperative effort, like with other county and city clinics.

DR. SCHEIDT: This is Peter again, and to answer the last question, the last part first, we encourage and expect a number of cooperative efforts. So it's anticipated that if your health department is not submitting a proposal to be a center but others are, that it's likely that those who do would need to--or would find it very helpful to partner, or have some similar arrangement with entities such as yourself with access to participants in family planning clinics as you describe.

Now I'm sorry, the first part of the question I didn't get.

QUESTIONER: Okay. Well, my first part is trying to define the type of clinic you might be interested in looking at in terms of your goal to recruit, you know, children in utero, for instance.

DR. SCHEIDT: We're not looking for any special kind of clinic. There are a number of—I mean, certainly, clinical facilities that are related to maternal and child health can be useful in carrying out this study. It is not a given or absolutely necessary that any given set or type of clinic is, you know, critical, but some, you know, can be quite useful. We don't have a preconceived notion of what this must look like.

QUESTIONER: Okay; thank you.

MR. QUACKENBOSS: It might be worthwhile mentioning that in terms of recruiting the prenatal—or the intent of the Study to be able to evaluate early pregnancy and even pre-pregnancy exposure—it was a subject of discussion and a consideration in terms of the sampling design, where we felt that the only feasible way to get early pregnancy exposures within, say, the first month of pregnancy, was to use a household recruitment approach, to identify women before they become pregnant, and to then follow them over a period of time and ask them to notify us as soon as they become pregnant.

And with some women who are intending pregnancy and therefore have a much higher probability of becoming pregnant, we would even provide them with fertility monitors and pregnancy test kits, so that we can ascertain their change in pregnancy status very early.

So we're looking at that as being probably a primary means of recruitment in the Study and then looking at clinics, other ways, mechanisms such as prenatal care providers in terms of making sure that we get full coverage of all live births that occur within the communities.

QUESTIONER: That's good; thank you so much.

MODERATOR: We have a question from the line of James Bailey in Benton County.

QUESTIONER: We're also a public health facility, and my initial question in large part's been answered somewhat by the previous questions and responses, but it's centered mainly around if one was operating as a vanguard center, the up-front contribution in terms of personnel and time. Is there anything that you could provide that might help there?

MS. KEIM: I think the best reference for that would be to look at the request for proposals on line. The Study plan there I think should give you a sense of the parameters, extent and breadth of the work that would be expected of staff. We are not posting a prescription for number of staff required, because we want to leave that flexible and ask the potential centers to think creatively about their strengths and their available staff and what they believe would need to be done to carry out the work described there in the Study plan or request for proposal. So I think the best reference is to take a look at that document.

DR. SCHEIDT: However, if your question might relate to support for that staff, we do anticipate that this is a federally funded study, and staff required to carry out the Study would be funded, you know, through funds for the Study.

QUESTIONER: I know the reference to the community piece was very interesting to us in that in the state of Arkansas, public health departments being a very important part in each of the counties in a hometown health improvement committee or coalition, and those coalitions do involve business, schools, hospitals, clergy, et cetera—truly a cross-section of the community. That is already in place, and this could be something, from our standpoint, that could roll into that very well.

MS. KEIM: That's fabulous.

DR. SCHEIDT: That sounds very interesting and is precisely why we did not prescribe what must be there, because there are creative and individual approaches in a variety of counties.

QUESTIONER: That answered my question. Thank you.

OPERATOR: The next question comes from the line of Eric Fine in Baltimore County.

QUESTIONER: Good afternoon. This is an extremely important study, and I congratulate you for all your planning. I had several questions.

Is there an award amount for the centers that would apply to be vanguard Study sites? Do you have a maximum award?

MS. KEIM: No, we have not posted the amount of the award. It depends on the quality of the proposals and how many centers we think we can award, given funds available for this fiscal year. I can say that this fiscal year, which is fiscal year 2005 for us in the federal government, which goes from now until the end of next September, we have approximately $12 million available to keep working on planning and move toward implementation of the Study as a whole. So we have these vanguard centers coming online, our coordinating center and other activities here at the federal level that those funds need to be applied toward.

Now, of course, in fiscal year 2006 and beyond, the funding needs increase quite substantially because of, obviously, the costs of recruitment, enrollment, and measures and follow-up. But I should mention that we expect this to be a federally funded effort through congressional appropriation and are optimistic in looking forward to seeing those appropriations available for the Study. So counties are not expected to kick in funds to pay for this.

QUESTIONER: A second question. I didn't see any reference in the description, and I haven't read the full Study plan, but references to the effects of nutrition or food additives, clearly these are things that have changed considerably over time and do impact on birth outcomes and so forth. That would be considered a focus of the Study?

DR. SCHEIDT: Yes, definitely. We consider those a class of exposure, and they are considered important data to gather for the Study. There's additional information about those kinds of measures and variables from a whole series of workshops that can be seen on the Web site under the tab "the research." And within that section, there's another section that actually posts the summaries of the many meetings and workshops that we've had in planning this study. Among them are workshops on measures for nutrition and supplements.

QUESTIONER: Okay. I assume that would include exposure to pesticides and other environmental chemicals. Will you be interfacing this data at all with the NHANES study as these kids age and move into the over-18 group? There's a considerable amount of federal resources committed to those measurements.

DR. SCHEIDT: Yes, we're well aware of those data and we're using those data in part for guidance of this study.

This study focuses on exposure-outcome relationships and causal inferences, whereas the NHANES data are cross-sectional and develop prevalence estimates. We see this study as an important complement to NHANES, providing insights into the potential effects and understanding the implications of what the ongoing NHANES study tells us about exposures and prevalence of exposures.

QUESTIONER: One last question. Baltimore County, Maryland, has about 700,000 population and 10,000 annual births. I'm assuming that we'll get some assistance, if I understood you, in stratifying the 250-odd births that we would be recruiting on an annual basis, because we have a tremendous amount of diversity within our county—geographic, ethnic, and so on.

MR. QUACKENBOSS: Yes, we'd be looking to the local center and, I think, you know, to you also where you have the resources or the ability or the data available to help in terms of identifying the characteristics of populations and communities, exposures that are of concern or that are known in the area, sources of exposure, and we could then use that information in helping to select the second-stage sample.

And then within the second-stage sample would be the identification of households and recruitment of women into the Study. And that may involve within the selected communities maybe all households that have women who are eligible, or maybe a subsample, depending upon the number of households that we would expect or number of women that we'd expect relative to the number of births that we would anticipate over the period.

DR. SCHEIDT: Yes, let me add that the coordinating center is charged with having the expertise to provide guidance and backup for secondary sample selection, under guidance and approval of the National Children's Study Program Office as well.

MR. QUACKENBOSS: The other thing I wanted to mention in response to your first question, Pete pointed out that the workshops are available under the research tab in terms of the Study description. But the other thing that's there are some of the Study hypotheses, which identify measures that would relate to those and relating to issues of nutrition and food additives. There are outcomes identified for obesity as well as certain other endpoints where we would have concerns about pesticide exposure as well as food additives in the diet. But the other hat that I wear is working on the exposure portions of the Study.

QUESTIONER: Great. Thank you.

OPERATOR: The next question comes from John McKellar in Genesee County.

QUESTIONER: Yes. Thank you. I have what I hope are just three quick questions. I confess I've not looked at the proposals online and I'm sure some of this is answered there. But it sounds like the Study centers, or perhaps they're clinical coordinating centers, will be agencies with whom you will contract to do the field work on your behalf and help the local communities, help them accomplish that. Is that correct?

DR. SCHEIDT: That's correct, to actually do the work to carry this out. And they form whatever relationships, partnerships, consortia necessary to do that.

QUESTIONER: Okay, great. Is there a deadline for those proposals, as to when you'll be deciding exactly who those folks are?

MS. KEIM: We expect to make awards for the vanguard centers next August or September. Proposals are due, I believe it's the middle of February, the end of January.

DR. SCHEIDT: No, February 16th.

MS. KEIM: The exact date is posted in the request for proposal. I urge you to reference that to make sure that date is correct. So you have a little bit of time if you're interested.

DR. SCHEIDT: But that's for the vanguard centers.

MS. KEIM: Yes, for the vanguard centers.

QUESTIONER: Okay, the question is when the proposals are due for the coordinating centers.

MS. KEIM: Oh, for the coordinating—there's a single clinical and data coordination center. That request for proposal is also posted, and proposals are due at the—

DR. SCHEIDT: January 20th.

MS. KEIM: Middle of January. January 20th.

QUESTIONER: Okay. Final question is, if the vanguard locales will be doing their recruitment in 2007, when would you expect recruitment to begin for the rest of the counties?

MS. KEIM: 2008, probably, around a year later.

QUESTIONER: Right. Okay. Thanks very much.

OPERATOR: The next question comes from the line of Richard Vogt in Douglas County.

QUESTIONER: Yes, hi. I'm just a little bit confused in terms of the sampling strategy or the recruitment strategy of the 250 individuals per county. I'm hearing that you're kind of leaving it up to a group within that particular county to make those decisions.

DR. SCHEIDT: Not really.

QUESTIONER: Well, okay. But can you be more specific as to how they're exactly going to be selected? Of course, a random sample would probably be best under these circumstances, but it sounds as though, in terms of recruitment, we're going to be trying to cajole specific centers or our health care providers to assist. How is that going to work in the whole mix of things, in terms of being a national study, if there are going to be some local decisions about how this is going to happen?

And a secondary concern is this issue surrounding recruiting individuals before birth. There can be a tremendous bias interjected into this particular process because, of course, lower socioeconomic individuals by and large may not have this advance planning for pregnancy, and we may be selecting them out with that particular process.

MR. QUACKENBOSS: Why don't I give you a little overview on the second and third stage of the sampling? For the second stage, we are looking at—in terms of local input in terms of defining the boundaries for geographic segments—starting, for example, with Census boundaries, neighborhood boundaries, or perhaps things like school catchment areas. But we want to try and avoid splitting a community down the center. So we would want input in terms of making sure that those boundaries make sense.

However, to maintain the integrity of the sample, it will be selected randomly, with probability proportional to size, possibly stratification by demographic factors and environmental factors. And given the size of the total study, there's probably some opportunity here to oversample certain areas of greater concern or certain demographic groups that we otherwise might under-represent in the Study if it was just done purely at random.

Then, moving to the third stage, would be the recruitment of Study participants. We anticipate this being primarily through a household recruitment approach where all households or a sample of households within those communities would be contacted, screened to identify women that are, say, between the ages of 18 and 40, and then they would be recruited into the Study. So we hope from that not to be biasing ourselves toward only those who are planning pregnancy, in terms of their eligibility to be in the Study.

However, our concern is that, to maximize the use of available resources, we were going to try and focus the measures—very early pregnancy on those that are intending pregnancy, given that they would have a much higher likelihood of becoming pregnant, say within a 4- to 6-month period—rotate in and out of different groups, and so they will essentially be replenishing that group of women who are intending to become pregnant.

In addition, we had some concern that we might miss some women through this approach, so we would look to the prenatal providers or other mechanisms in terms of including women who become pregnant but have not previously been recruited or enrolled into the Study, including those that may first present at birth. So we're trying to avoid the kind of bias that you're discussing there.

DR. SCHEIDT: But we understand those potential biases are there, and to assure that we at least understand them, we will also monitor live births for the segments and catchment area and, where necessary, even add to the cohort at the time of birth if significant biases exist, so that we will know who are the infants that are born and be able to understand and measure those biases.

QUESTIONER: Okay. Thank you. Obviously you have thought about this a lot more than the materials that you had sent out, and that's helpful to know that. Thank you.

OPERATOR: We have a question from the line of Brian Letourneau in Durham County.

QUESTIONER: Yes, I think that my questions have been answered. Thank you very much.

OPERATOR: We have Thomas Lachocki in El Paso County.

QUESTIONER: My name is Tom Lachocki. I'd like to get a little more information on how the studiers ensure that the Study doesn't introduce bias into all the people that are being studied.

DR. SCHEIDT: By virtue of—let me see if I understand your assumptions.

QUESTIONER: Let me just clarify. My understanding is the Study is going to be performed in a number of these different vanguard locations and the results are going to be projected and help guide policy across the whole nation. But clearly, when there is involvement with studiers relative to participants, that interaction could introduce a bias into the people that are being studied, reducing the ability to extrapolate that information to the rest of the country. How is that going to be handled?

DR. SCHEIDT: We have thought about and discussed this issue a great deal. We know that there is not only the risk, the probability of the kind of information generated by the Study affecting behavior of the individuals participating and the communities participating.

Where we learn information that places an individual at risk, we think the obligations of informing those individuals—if it's a known risk—we think our obligations of informing the individual about that risk are above the concerns about reducing or biasing the observations of the Study. We think that the size of the Study and the number of observations will allow us to observe relatively small differences, and therefore we can still learn what we need to learn about relationships. But those relationships may be reduced and in fact biased by participation in the Study. That's an unavoidable consequence, and we think the benefits to be gained from the Study far outweigh those difficulties.

QUESTIONER: I think one thing to focus on here is that the intent of the Study is to look at exposure-response relationship. And to do that in the context of what are some of the biomedical mechanisms relating exposure to response, in that respect it's characterized as more of an analytic study as opposed to something like the NHANES study that was mentioned before, which is more of a descriptive study to get prevalence estimates in the population. And the feeling is that, given the other information that we will have and doing the analyses in a more model-based type analysis and testing of hypotheses, that the effects of those kinds of bias might be minimized. But certainly some factors are less prone to be biased than others, but I'm glad to hear that's a big consideration.

Let me ask another question. When will the surveys be developed to assess what role exercise or exercise facilities, availability of exercise facilities, et cetera, have in that person's development?

MR. QUACKENBOSS: Pete, I'll go ahead and handle it since I've just been with that workshop.

DR. SCHEIDT: Okay, Jim.

MR. QUACKENBOSS: There are probably two areas that we would look at with regard to that. One is in terms of impact of exercise, physical activity on the mother and the developing fetus. And that's a very early stage in the Study, obviously. So we have had a workshop that did identify where you can find information on physical activity about a year ago. Recently, last week, we had a workshop looking at time use, and that relates in terms of where people spend time, what they're doing there, and so it's connected in some ways to this same issue. And we are looking at survey-type approaches to assessing physical activity as well as, say, motion sensors or other technical methods of trying to assess activity level of the individual.

In addition, the Study is—some of the hypotheses for the Study look at the role of the community and the kinds of facilities that are available in the community or the characteristics of the community in terms of access to parks, walking areas, and the like, and how that might impact on the likelihood that people are exercising, and then on some of the subsequent outcomes.

QUESTIONER: Would you know if there will be anything in there on swimming pools, aquatic facilities?

MR. QUACKENBOSS: I would think that we would be looking at all types of physical activity. Swimming pools also bring with them concerns in terms of exposure to some of the disinfectant byproducts, and so we would be wanting to assess that as a source of exposure as well as a physical activity.

MS. SHREEVE: I think we should keep moving through our queue of questions. I think we have a lot of people holding on the phone.

QUESTIONER: Thank you.

OPERATOR: The next question comes from David Goolsby in Spartanburg.

QUESTIONER: This is David Goolsby. We're with Public Health in Spartanburg County, South Carolina. I understand that you've had similar conversations with local county government officials. And before we start building partnerships and having similar conversations, could you summarize those other institutions or partners and medical systems that have already been a party to this information, so that we minimize the redundancy?

MS. KEIM: The packet that we sent to all of you on November 16th was very similar, or actually identical, to a packet that we sent to medical schools, both the pediatric and obstetric departments there, and their head of research, and schools of public health will be getting this information next week. Also individuals who work in maternal and child health at state health departments received a similar packet, and governors' offices in the states where there are Study locations.

So those people have received information very similar to what you have. The conference calls we've had, this one and the one yesterday, are the only conference calls we've had of this nature.

QUESTIONER: There has not been or perhaps is not yet a plan to speak with local hospital systems or municipal governments?

MS. KEIM: Well, yesterday we spoke with county governments, but in terms of city or town governments, since the Study is very much at a county level right now, we've been focusing just this initial outreach to counties. We hope to get to that level of specificity, maybe with your help even, in identifying the folks who are best able to engage at that level. I think that will become more and more clear as we get centers lined up and get closer to recruitment in some of these locations when we know exactly where the participants are living that will be invited to participate. So we're just starting, so we started with counties.

QUESTIONER: Good step, thank you.

OPERATOR: Next question comes from the line of Althea Kamau in Honolulu.

QUESTIONER: That's Kamau, but this is Linda Rosen from the Hawaii State Health Department, and my question was partially answered by the caller who asked about the bias, potential bias in recruitment in trying to recruit families who were planning pregnancy. Since we have, I think, on the small side in terms of annual births—and there are about 16,000 for the state—and most of the population is in Honolulu County, but, you know, we're talking about maybe 14,000 births. So I'm interested to know a little bit more.

You've talked about initial and secondary and third phase recruitment, but since it's critical for us to try to understand whether we could really anticipate how we would recruit 250 a year, could you expand a little bit about in this initial phase what is that 250 supposed to consist of? At what point do you have to recruit them?

MR. QUACKENBOSS: Let me respond to that, at least initially. That 250 should look like the entire number of births that you have—what did you say, 1,400?

QUESTIONER: I'm guessing it's about 14,000—not 1,400.

MR. QUACKENBOSS: So you have 50,000 births over a 4-year period that were used for the sample selection. And so our aim is that that 250 a year to 1,000 for the total sample, should be representative of the 14,000—if that's what you have in Honolulu, or Oahu, which is the county I think.

QUESTIONER: But I think that that's the problem, as was mentioned. We don't even have a 50 percent. We monitor this, you know, in surveys, and we don't even have 50 percent of births having been planned or anticipated. It varies between different groups. So for us to recruit 250,

which was a representative sample of our population, for those groups that don't have a high incidence of early planning of pregnancy would be extremely difficult.

MR. QUACKENBOSS: And for that reason—and we understand that, and anticipate that, and for that reason the use of obstetric care providers and other community approaches to recruit the sample will be very important, and adjustments of that to appropriately reflect the distribution of your site would be appropriate as well.

QUESTIONER: Well, thank you, that's helpful, because then we can be more realistic. Just a quick comment though about when you mention in the tertiary sample, I understand following women in anticipation of pregnancy could be expensive if the incidence is in fact low, but I wondered if you considered early on at least creating some of that sample, because then you have more time for them to become pregnant, and maybe the investment in following them in those years when they're not pregnant could be relatively small, but you could be creating a concurrent cohort that would maybe help address that selection bias that we're talking about.

MR. QUACKENBOSS: That's exactly the approach, to enroll the larger cohort of women during the first year, and then to follow that group for up to the 4-year period.

QUESTIONER: Okay. So we will then in that 250 actually be including women who are not pregnant?

MR. QUACKENBOSS: Correct. Yes, 250 are births. We're expecting on the order of about a 10 to 1 to 12 to 1 ratio of needing that many more households or women—I think it's households—that would need to be contacted to enroll enough age-eligible women to then follow them over a 4-year period to get the 1,000 births.

QUESTIONER: Okay. So that's actually part of the task there in the first year too.

MR. QUACKENBOSS: Correct.

OPERATOR: The next question comes from the line of Tupper Morehead in Morgan County.

QUESTIONER: I'm in Morgan County, Tennessee, and what I'm hearing is that the role of the local county health department is more of a role of facilitation and liaison with the medical community and collaboration? Is that correct?

DR. SCHEIDT: Not necessarily, but it could be. In other words, we're not prejudging that a capable, well-versed county health department with broad resources could not itself be a center. But we anticipate that the—not even necessarily the majority, but that a number of the centers are likely to be academic centers with relationships with county health departments.

QUESTIONER: I see. Morgan County is a county of about—a very rural county of about 20,000 people in an Appalachian part of the country, and there's not—I mean the women don't deliver in that county. They go elsewhere. So there's only about six employees in the health department.

DR. SCHEIDT: Recruiting 250 will be difficult.

QUESTIONER: I'm just trying to figure out what a county that small, how they will enter into this study.

MS. KEIM: I think one thing—I refer you to the list of Study sites, either on our Web site or in the mail materials. We actually—based on the data we had about the number of births in Morgan County, have clustered it or grouped it with Cumberland County to get sort of a possible critical mass of potential participants between the two counties. So they are grouped together for the purposes of recruitment and carrying out the Study.

DR. SCHEIDT: So you're not alone.

MS. KEIM: You're not alone.

QUESTIONER: Okay.

OPERATOR: We have a question from the line of Carlotta Ellis. Your question, please?

QUESTIONER: Hi. Yes. I am from Stark County in rural North Dakota, and I just had a question because we barely have 269 pregnancies in this county per year, and so our births are maybe 200 to 250 births. I'm not quite sure how we would be able to meet the 250 requirement.

And then the other question I have is what is there as an incentive for the parent or the women to be involved? Has anybody figured out what their time commitment would be over the period of time?

DR. SCHEIDT: Yes, let me answer those. There are a group of counties, of rural counties, of non-metropolitan counties like yours that we now realize the number of live births is sufficiently small that we think we will need to add additional counties in order to reach the critical mass that we discussed earlier. And I think that your county is among that. So we will be revising the request for proposals and update that with the additional counties where that's necessary. So let me invite you to check the Web site for the revised RFP that will be out within a week or so.

With regard to incentives, yes, we do anticipate incentives will be important. One form of incentive will be to compensate those mothers and families that participate for the inconvenience and the expenses of participating in the Study, child care, transportation, and a compensation for inconvenience of a monetary payment for time that they spend, you know, giving information and data and samples in the Study. Those will be appropriate according to ethical guidelines that have been well worked out for conducting this kind of research in a variety of ways.

In addition, however, we think that an even more important incentive will be what mothers and families learn about the environment and the growth and development and health of their children as a consequence of participating in the Study. And our experience with other studies,

like the Women's Health Initiative, has affirmed that in fact participants in the Women's Health Initiative, though they have financial compensations, tend to view that what they learn through their participation is the most valuable part of motivating them to continue in the Study.

Does that answer your question?

QUESTIONER: Yes, it did answer my question. Hopefully, when you expand the counties you would be looking at contingent counties, you know, counties that might—

DR. SCHEIDT: It would have to be adjacent to your county.

QUESTIONER: We're a district health unit and we cover 8 counties, but even then, our amount of births would maybe go up to Stark County. So, you know, I guess our concern—we're hearing 14,000 births and people are concerned about recruiting 250, and you know, it's unrealistic for us to have 250.

DR. SCHEIDT: Yes, we understand that. We would like to emphasize though that we very deliberately, in drawing the sample, tried to make sure that we did include areas like yours. If we were to just simply do, you know, the normal random type sampling, we could miss areas that do not have the flavor of rural America. And so we want to work with you in terms of making sure that these areas are well represented within the Study.

QUESTIONER: Well, I am pleased that you did include rural areas, I guess, and maybe, you know, the adjustment of maybe we can't do 250, but we may end up with a smaller amount or we need to add additional counties.

DR. SCHEIDT: Yes.

MS. KEIM: Let's take two more questions from the line.

OPERATOR: We have a question from Troy Jacobs in Orange County.

QUESTIONER: Hi. This is Dr. Troy Jacobs, Orange County, California. And I have a question regarding the—you have three competitive processes, one for a coordinating center, one for the vanguard sites, and then eventually one for the Study locations. As Orange County's a vanguard site, given the sampling is based on population, a number of the other Study locations are in surrounding counties. What expectations do you have for the vanguard sites to be involved in the other Study locations or collaboration over the subsequent years, or is that really going to be a task of the coordinating center solely?

DR. SCHEIDT: Your circumstance is exactly why it was necessary to announce the sites for the entire 96 sites, rather than just the vanguards, at this circumstance. So that the potential centers in your area can understand what is now and what will be required of them. And we do expect subsequent competition, and we expect the subsequent competition to be between all of the potential centers in your area. So that a center that is selected to carry out the vanguard

responsibility in Orange County may also compete with others to do the work in the other sites that are present in Southern California as well, and we anticipate that other centers in your area will also compete.

QUESTIONER: Is there also potential for collaboration though across these jurisdictions?

DR. SCHEIDT: Yes, indeed.

QUESTIONER: Okay.

DR. SCHEIDT: We would encourage that.

QUESTIONER: Okay. Thank you.

MS. KEIM: Okay. One more question from the line.

OPERATOR: We have a question from Rhonda Payne in Bradley County. Your question, please.

QUESTIONER: Yes. I was wondering about—I guess my question would be more about how are you going to handle situations where—like in my area of Tennessee, Southeast Tennessee, there are a lot of people that can't read and write, and how—when it comes to recruiting, how is it that you would keep….[Technical interruption.]

DR. SCHEIDT: I think we lost her. Hello?

OPERATOR: Pardon me, ma'am, one moment. Your line is open.

MS. KEIM: Hello? Are you still there?

QUESTIONER: Hello? Can you hear me?

MS. KEIM: Yes.

QUESTIONER: Now can you hear me?

MS. KEIM: Yes, go ahead.

QUESTIONER: Okay. I guess my question was how do you keep from having a recruiter bias toward your recruitee, you know, if they can't read or they can't write, they don't have a telephone, things like that?

DR. SCHEIDT: We understand those risks and biases and have to actively plan to compensate for them. That means translating into necessary languages for subpopulations that are in the area, and providing the necessary support and extra effort required to not lose the kinds of participants that you described, because they are in fact at even greater risk, and have exposures that are of

special interest to us. So we will be monitoring—the coordinating center will be working closely with the Study centers to provide resources and instruction and coaching, and to assure that every effort is made to minimize the kind of bias, or potential bias that you described.

QUESTIONER: Thank you.

MS. KEIM: That's the conclusion of today's call. We want to thank you very much for participating. We know you all are very, very busy, and we appreciate your time and interest and participating in the call today about the National Children's Study. If there are remaining questions or if anyone's interested in asking a follow-up question, please give us a call or send us an e-mail. I'll give you our phone number again. It's 301-594-9147. Our e-mail address is ncs@mail.nih.gov. Those ways to contact us are also listed on our Web site, www.nationalchildrensstudy.gov.

We're very pleased to have you with us as we embark on this remarkable study, and we have high hopes that it will very much change children's health and our understanding of the impact of the environments in which children live in the next few years and for the next several generations.

So thank you again for your time, and we look forward to speaking with you again soon.

OPERATOR: Thank you, ladies and gentlemen. This does conclude the conference call. You may now disconnect.

[End of conference call.]